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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,990	HEIRLER, HORST	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *4,7 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *19 May 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are presented for examination.

Applicant's claim for priority under 35 U.S.C. 119(a)-(d) to German Patent Application No. 10254584.7-41 filed November 22, 2002 has been acknowledged. Applicant's certified copy of German Application 10254584.7-41 has been received and entered into the application. However, the Office has not received a translation of the same. Applicant's Information Disclosure Statement (IDS) filed May 19, 2004 has also been received and entered into the application. As reflected by the attached, completed copy of substitute form PTO-1449 (one page total), the Examiner has considered the cited references.

Claim Objections

The following claims are objected to for lacking sufficient antecedent basis:

(i) claims 2, 7, 10-11 and 13-14 are objected to for lacking sufficient antecedent basis for the limitation of "the fat phase" as recited, for example, in line 1 of claim 2. Reference to such a limitation does not appear in the previous claims from which claim 2 depends.

(ii) claims 14-16 and 18 are objected to for lacking sufficient antecedent basis for the limitation "the aqueous phase" as recited, for example, in line 2 of claim 14. Reference to such a limitation does not appear in the previous claims from which claim 14 depends.

(iii) claim 11 is objected to for lacking sufficient antecedent basis for the limitation "with regard to the highly unsaturated fatty acids" as recited in lines 3-4 of the claim. Reference to such a limitation does not appear in the previous claims from which claim 11 depends.

Appropriate correction is required.

Claim 4 is objected to because the word "triglyceride" is misspelled at line 2 of the claim.

Claim 7 is objected to because the word "multiple" is misspelled at line 2 of the claim.

Objection to the Specification

The disclosure is objected to because of the following informalities:

(i) the word "omega" is misspelled at page 5, para. [0012], line 6 of the disclosure; and

(ii) the word "arteriosclerosis" is misspelled at page 6, paragraph [0018], line 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

The MPEP sets forth the following:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what Applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph, with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expressions "about 80% and the aqueous phase is about 20%"

(claim 14) and "about 60 to 65% and the aqueous phase is 35 to 40%" (claim 14) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular percentage amount is included in or excluded from the present claims and what degree of variability outside the recited percentages is within the scope of the claims. Thus, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims. Thus, the claims do not meet the tenor and express requirements of 35 U.S.C. §112, second paragraph, and claims 14-19 are, therefore, properly rejected.

II Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

The term "highly" in the expression "highly unsaturated fatty acids" (see claim 11, for example) is a relative term that render the claims indefinite. The expression is not defined by the claims, the specification does not provide any direction or standard for ascertaining the requisite degree, and, thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Use of such a phrase would invite subjective interpretations of whether or not a particular unsaturated fatty acid is included or excluded from the present claims and whether the degree of unsaturation meets the limitation of "highly unsaturated" as recited in the present claims. Thus, it is the Examiner's position that the public would not be informed of the

boundaries of what constitutes infringement of the present claims. Such subjective determinations are inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and claims 11-13 are, therefore, considered properly rejected.

III Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

The phrase "sufficient to regulate and normalize fat metabolism" in the expression "in an amount sufficient to regulate and normalize fat metabolism in the subject" is a relative expression that renders the claims indefinite. The expression is not defined by the claims, the specification does not provide any direction or standard for ascertaining whether fat metabolism has been regulated and normalized in accordance with the present invention and, thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Use of such a phrase would invite subjective interpretations of whether or not fat metabolism has been regulated and normalized to a degree that is included or excluded from the present claims. Furthermore, the Examiner notes that the metabolic rate of fat is a characteristic that is unique to a particular individual. Thus, determination of the degree modulation of fat metabolism must be altered to be considered "regulated" or "normalized" for a general population of subjects is highly subjective and would vary per individual, as would the amount of medium chain triglycerides required to induce a particular degree of modulation per subject. In the absence of further direction in the present disclosure or claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims.

Such subjective determinations are inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and claims 1-19 are, therefore, considered properly rejected.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (International Patent Application WO 97/38593; 1997).

Bell et al. teaches a diabetic supplement bar used for the treatment of nighttime hypoglycemia in a diabetic patient, wherein the supplement bar includes about 2-40% by weight of lipid. Bell et al. discloses that the lipid source comprises a mixture of medium chain triglycerides and long chain triglycerides (page 2, lines 31-34 and page 4, lines 13-14). Bell et al. further teaches that the lipid source should be added to the diabetic supplement bar in the amounts sufficient to delay gastric emptying (page 4, lines 18-19) and that the lipid source may be present in what the Examiner considers to be a substantial amount, i.e., up to 40% (page 3, line 17).

The Examiner has noted that Bell et al. discloses the use of "amounts sufficient to delay gastric emptying" (see page 4, lines 18-19), which may be up to 40% of the total weight of the composition (page 3, line 17). While the present claim recites "an amount sufficient to regulate

and normalize fat metabolism in the subject", Applicant has failed to provide any direction in the specification as to the dosage amounts that underlie this functional statement (see also "Claim Rejections-35 U.S.C. 112, Second Paragraph" above). In the absence of factual evidence to the contrary delineating why the amounts of the present claims are not anticipated by Bell et al., the Examiner considers it reasonable to conclude that the teachings of Bell et al., i.e., the use of amounts of lipid source sufficient to delay gastric emptying (see page 4, lines 18-19) in an amount of up to 40% of the total weight of the composition (page 3, line 17), to directly anticipate the amounts encompassed by the functional recitation in present claim 1, i.e., an amount sufficient to regulate and normalize fat metabolism in the subject (see claim 1, lines 3-4). Applicant's attention is further drawn to the MPEP at §2113, which states, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Furthermore, while the disclosure of Bell et al. teaches a mixture of medium-chain and long-chain triglycerides, such does not change the fact that Bell et al. expressly discloses the administration of medium-chain triglycerides in a dietary supplement bar for diabetic patients. Thus, the disclosure of a mixture of medium and long-chain triglycerides is considered by the Examiner to meet the limitations of "medium-chain triglycerides" **and** "a composition comprising medium-chain triglycerides" as recited in present claim 1. The Examiner further notes that the present claim uses the word "comprising", which is considered open transitional claim language and allows for the use of other components with the active agent recited in the present claim (see MPEP §2111.03 [R-2] for a discussion of transitional phrases).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. for the reasons of record set forth above as applied to claim 1, and further in view of The Merck Index (Monographs 5382, 5383, 6788, 9918 and 9932), Zawistowski et al. (WO 01/91587 A2; 2001), Laughlin et al. (U.S. Patent No. 5,470,839; 1995), Stedman's Medical Dictionary (22nd Edition, 1973; p.1400), Mendy (U.S. Patent No. 4,407,821; 1983) and DeMichele et al. (U.S. Patent No. 5,780,451; 1998).

Bell et al. further teaches that the source of medium-chain triglycerides may be any one of coconut oil, macadamia oil, palm oil, palm kernel oil or mixtures thereof (page 2, lines 34-35). Long-chain triglycerides may be obtained from any one of canola oil, safflower oil, sunflower oil, corn oil, olive oil, menhaden oil, peanut oil, or mixtures thereof (page 2, lines 35-37). Bell et al. also discloses the use of simple carbohydrates, such as glucose or dextrose (page 2, lines 21-25), protein, such as whey, lactalbumin, casein, egg white, egg solids, soy and delactosed milk solid (page 2, lines 26-30), complex carbohydrates, such as uncooked starch, nuts, barley, bulger, pasta, parboiled rice or dried legumes (page 3, lines 1-6), as well as vitamins and minerals in accordance with, or approximately, the Recommended Dietary Allowance (RDA) (now called

the Reference Daily Intake (RDI), amounts (page 3, lines 7-10). Bell et al. teaches the additional use of emulsifiers for stability of the supplement bar (page 5, lines 1-2) and/or flavoring, such as flavored extracts, volatile oils, chocolate flavoring, peanut butter flavoring, cookie crumbs, vanilla or any commercially available flavoring, to make the supplement bar more palatable (page 5, lines 3-9). Particular flavorings disclosed by Bell et al. include pure anise extract, imitation banana extract, imitation cherry extract, chocolate extract, pure lemon extract, pure orange extract, pure peppermint extract, imitation pineapple extract, imitation rum extract, imitation strawberry extract, pure vanilla extract, balm oil, bay oil, bergamot oil, cedarwood oil, cherry oil, cinnamon oil, clove oil, origanum oil or peppermint oil (page 7, lines 2-9). Bell et al. further teaches the administration of the supplement to a diabetic patient, which is defined by the reference as any patient who requires insulin injections to maintain blood glucose levels as close as possible to a normal range, e.g., Type I or Type II diabetes (page 5, lines 33-36).

The differences between the Bell et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the use of oleic acid or linoleic acid as unsaturated triglycerides;

(ii) the use of alpha-linolenic acid, eicosapentaenoic acid and/or docosahexaenoic acid;

(iii) the use of butter flavor or additional vitamins and nutrients, including fat-soluble vitamins, beta-carotene, folic acid, zinc, chromium or manganese, for example, as recited in present claims 11-14 and 15-19; and

(iv) the presently claimed dosage amounts of triglycerides, fatty acids or additional nutrients and the presently claimed percentages of the fat phase versus the aqueous phase of the composition as recited in present claim 14.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Bell et al. expressly discloses that medium- or long-chain triglycerides may be gleaned from sources such as coconut oil, macadamia oil, palm oil, palm kernel oil, canola oil, safflower oil, sunflower oil, corn oil, olive oil, menhaden oil, peanut oil, or mixtures thereof (page 2, lines 34-37). While Bell et al. does not expressly teach the use of oleic or linoleic acid as a component of the composition, it was well known in the art that oleic acid is obtained from olive oil (see Merck Index, Monograph 6788, p.1079) and linoleic acid is obtained from any one of peanut, sunflower or safflower oil (see Merck Index, Monograph 5382, p.867). It would have been apparent to a person of ordinary skill in the art that olive and/or peanut, sunflower or safflower oil sources would necessarily provide oleic and/or linoleic acid as fatty acid components. The disclosure of such sources that are known in the art to contain oleic and/or linoleic acid as the major component is considered to meet the limitation of oleic acid and linoleic acid as recited in present claims 2-5.

Furthermore, the Examiner notes the recitation of "oleic acid as monounsaturated triglyceride" in present claim 4 and "linoleic acid as double-unsaturated triglyceride" in present claim 5. While such a limitation has been considered during examination, such is not considered to impart a characteristic or property to the claimed oleic acid or linoleic acid that is not necessarily present in the compound as it is known in the prior art (see The Merck Index, Monographs 5382 and 6788). Oleic acid is known in the art to be monounsaturated (see

structural depiction, Merck Index, Monograph 6788), in that it has one carbon-carbon double bond, and linoleic acid is also known in the art to be double-unsaturated (see structural depiction, Merck Index, Monograph 5382), in that it has two carbon-carbon double bonds. Thus, such a recitation in present claims 4 and 5 is not considered to be a patentable distinction, but rather a further description of the structural properties of the triglyceride component.

(ii) Although Bell et al. does not expressly teach the use of alpha-linolenic, eicosapentaen or docosahexaen acid, use of such fatty acid components in nutritional compositions useful for the treatment of patients with diabetes was well known in the art at the time of the invention. Zawistowski et al. (WO 01/91587 A2; 2001) teaches a nutritional supplement composition as a pharmaceutical dosage form or a food nutraceutical composition, such as margarines or spreads (page 20, lines 7-8) useful for the treatment of patients with Type II diabetes (page 4, last paragraph bridging to page 5), comprising long-chain triglycerides wherein the long chain residues are derived from linolenic (known to be equivalent to alpha-linolenic acid, see The Merck Index, Monograph 5383, page 867), eicosapentanoic or docosahexaenoic acid (see Zawistowski et al., page 10, line 1-page 11, line 15). It would, therefore, have been obvious to a person of ordinary skill in the art at the time of the invention to employ any one of these long-chain triglycerides in the disclosed composition of Bell et al. in light of the general teaching of long-chain triglycerides. Based on the teachings of Zawistowski et al., who discloses the use of such long-chain triglyceride components, such as linolenic, eicosapentanoic or docosahexaenoic acid, in nutritional supplements for diabetic patients, such a person would have been motivated to use such long-chain triglycerides in the composition disclosed by Bell et al. in order to improve the efficacy and therapeutic benefit of the composition.

Furthermore, the Examiner notes the recitation of "alpha-linolenic acid as triple-unsaturated triglyceride" in present claim 6 and "eicosapentaen acid and/or docoshexaen acid as multiple-unsaturated triglycerides" in present claim 7. While such a limitation has been considered during examination, such is not considered to impart a characteristic or property to the claimed alpha-linolenic acid or eicosapentaen or docosahexaen acid that is not necessarily present in the compound as it is known in the prior art (see The Merck Index, Monographs 5382 and 6788). Alpha-linolenic acid is known in the art to be triple-unsaturated (see structural depiction, Merck Index, Monograph 5383), in that it has three carbon-carbon double bonds, and both eicosapentaen and docosahexaen acid triglycerides are also known in the art to be polyunsaturated (see Zawistowski et al., page 13, lines 15-17). Thus, such a recitation in present claims 6 and 7 is not considered to be a patentable distinction, but rather a further description of the structural properties of the triglyceride component.

(iii) Bell et al. generally discloses the use of vitamins and minerals in accordance with the Recommended Dietary Allowance (RDA) (now called the Reference Daily Intake (RDI), amounts (see page 3, lines 7-10), but does not expressly teach the use of beta-carotene, vitamins A, D, D3, E, C, B1, B2, B6, B12, retinyl palmitate, RRR-alpha-tocopheryl acetate, folic acid, niacin, zinc, chromium or manganese. However, such vitamins and mineral were well known in the art at the time of the invention, particularly for use in nutritional supplement compositions for the treatment of diabetes. Laughlin et al. (U.S. Patent No. 5,470,839; 1995) teaches an enteral nutritional formulation for diabetics, comprising any one of the following vitamins or mineral nutrients known in the art: vitamin A, beta-carotene, vitamin D, vitamin E, vitamin C, folic acid, thiamine (known in the art to be synonymous to vitamin B1, see Stedman's Medical Dictionary,

p.1400), riboflavin (known in the art to be synonymous to vitamin B2, see also Stedman's Medical Dictionary, p.1400), vitamin B6, vitamin B12, niacin, manganese, zinc and chromium (see Example, col.6).

While Laughlin et al. does not expressly teach vitamin D3, retinyl palmitate, ascorbyl palmitate or RRR-alpha-tocopheryl acetate, each was well known in the art as a formulation of, respectively, vitamin D, vitamin A, vitamin C or vitamin E. Stedman's Medical Dictionary has been relied upon to show that vitamin D3 was known in the art to be a type of vitamin D (see Stedman's Medical Dictionary, page 1400) and The Merck Index has been relied upon to show that vitamin A palmitate, or retinyl palmitate was a known formulation of vitamin A (see The Merck Index, Monograph 9918, page 1576). Mendy (U.S. Patent No. 4,407,821; 1983) teaches the pharmaceutical use of vitamin C in the form of ascorbyl palmitate for a lipid composition for the treatment of diabetics (see col.5, lines 35-37, 54-57 and col.6, lines 29-33) and DeMichele et al. (U.S. Patent No. 5,780,451; 1998) teaches the use of d-alpha-tocopheryl acetate (R,R,R) (col.23, Table 14, line 10) in an enteral nutritional product (see abstract, for example and The Merck Index at Monograph 9932 to show that d-alpha-tocopheryl acetate is a known formulation of vitamin E). Thus, it would have been well within the purview of a person of ordinary skill in the art at the time of the invention to employ any one or more of the vitamins or formulations of vitamins (e.g., ascorbyl palmitate, etc.) and minerals well known in the art at the time of the invention in the disclosed composition of Bell et al., who generally discloses the use of vitamins and minerals. Such a person would have been motivated to do so in order to augment the product with other required essential nutrients, which would, thus, enhance the therapeutic benefit of the composition.

Furthermore, while Bell et al. generally discloses the use of flavored extracts, volatile oils, chocolate flavoring, peanut butter flavoring, cookie crumbs, vanilla or any commercially available flavoring, to make the supplement bar more palatable (page 5, lines 3-9), Bell et al. is silent as to the use of butter flavor. However, it would have been apparent to a person of ordinary skill in the art at the time of the invention to employ a butter flavor in the formulation of certain types of nutritional products, such as margarines, spreads or other savory food products, for which such a flavoring would enhance the palatability of the product. Such a person would have been motivated to employ such a flavor in order promote compliance with a regimen of dietary supplementation by improving the taste and flavor of the product.

(iv) Although Bell et al. simply discloses 2-40% of lipids (i.e., a mixture of medium-chain and long-chain triglycerides, see abstract, for example, and page 2, lines 31-38), the reference does not particularly disclose the presently claimed amounts of medium-chain triglycerides, saturated long-chain triglycerides, or any one or more of the vitamins or minerals recited in present claims 11-13 and 15-19. However, the determination of the optimum dosage regimen and ratios of components of the composition to treat a subject with diabetes mellitus with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, including age, weight, sex, diet, medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would

have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Furthermore, while Applicant has presently claimed a particular range of percentages of the fat phase versus the aqueous phase, such a determination of the appropriate amount of fat phase and aqueous phase would be directly dependent on the dosages of fat components and the dosages of the aqueous components that would have been determined by the skilled artisan, taking into account any one or more of the factors described above in the preceding paragraph, and would be reasonably expected to vary among subjects. Thus, the percentage of the fat phase and the percentage of the aqueous phase would also be expected to vary widely and, in the absence of evidence to the contrary, such are not seen to be inconsistent with the percentages of fat phase and the percentages of aqueous phase that would have been determined by the skilled artisan.

Conclusion

Rejection of claims 1-19 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 22, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614